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(54) Pharmaceutical Compositions for Treating Viral Infections

(72) Pamukoff, Nicola,
Canada

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A B S T R A C T

Herpes virus infections and common cold viral infections in mammals are treated by application to the site of infection, of a formulation comprising glycerine, ethyl alcohol and an alkali metal halide.

The present invention provid s a novel pharmaceutical composition for use in treating viral infections in mammals, of the herpes viral family or common cold virus, by topical application to the external site of the infection. The composition comprises simple, economical ingredients in specified proportions, is safe and easy to prepare and apply, by the patient, and provides rapid alleviation of symptoms and sufferings of such virus infections.

Thus according to one aspect of the present invention, there is provided a pharmaceutical composition for use in topical application to alleviate virus infections of the herpes family of viruses and common cold virus, which comprises from about 2.5 to 5.0 parts by weight of glycerine, from about 1 to about 10 parts by weight of ethyl alcohol, and from 0 to about 1 part by weight of a physiologically acceptable alkali metal halide salt.

Preferably, such formulations are provided in a pharmaceutically acceptable carrier base. In a preferred embodiment of the invention, a liquid formulation is used, in which the above ingredients are dissolved in water, a suitable amount of water for use with the above formulation being from about 80 to about 120 parts by weight. The ingredients dissolve readily in water in the required amounts. It is, however, preferable that the solution of the pharmaceutical composition as above be relatively freshly made up, e.g. within about four weeks of use, since glycerine when used in amounts towards the upper limit of the specified range tends to come out of solution

after a p riod of time, unless the solution is kept in a cold environment.

Th above formulation may also be prepared as a cream, using a standard cream base as carrier, including physiologically acceptable waxes, gums, emollients and the like, as is well-known in the art. A suitable relative amount of carrier to form a cream with the formulation of the invention is in the range 80-120 parts by weight.

The formulation according to the present invention may of course include other physiologically acceptable, inert ingredients in addition to those specified above, to improve the esthetic qualities thereof. Thus, colorants, perfumes, etc., may be added, in amounts sufficient to impart esthetic quality improvements thereto, but not sufficient to interfere with the general effectiveness of the composition.

According to a further aspect of the present invention, there is provided a process for treating viral infections in mammals, which comprises the topical administration to the virally infected site of the mammal of an effective amount of a pharmaceutical composition comprising from about 2.5 to about 5 parts by weight of glycerine, from about 1 to about 10 parts by weight of ethyl alcohol, and from about 0 to about 1 part by weight of a physiologically acceptable alkali metal halide salt.

For treatment of cold virus infections with compositions according to the present invention, it is preferred to use a liquid, solution formulation, and to apply it as nasal drops, deposited into the nostril of the patient, and thence

into the nasal and post-nasal passageways. Suitably, the sufferer applies about 1-2 cc of the liquid solution formulation e.g. from a dropper, directly into the nostrils, initially at intervals of about 1 hour, but gradually decreasing the frequency of application, e.g. to 2 hours or longer, as the symptoms of the cold virus infection start to recede. In practice it is found that the patient's discomfort resulting from the cold viral infection is effectively completely alleviated after about 48 hours of the above treatment with the formulation according to the present invention.

In treating the sore or blister manifesting a herpes viral infection, either liquid or cream formulations can be suitably used. The liquid formulation is suitably applied, at room temperature, by means of a swab or other suitable applicator, to the location of the infection. Such application to the location is repeated at intervals of about 1 hour, until the patient experiences an alleviation of the pain and can observe a reduction in the size and swelling of the sore, whereupon the frequency of dosage can be reduced, e.g. to intervals of about 2 hours. Quicker and more effective treatment is obtained, of course, if applications start during the early visible manifestations of the infection. If application of the formulations according to the invention commences before the sores or blisters burst, a noticeable decrease in the swelling and a substantial relief of the discomfort is obtained after about 24 hours, whereupon the frequency of application can be reduced. After three days, with

very infrequent application during the third day, the visible and painful manifestations of the inf ction hav normally disappeared.

If, however, treatment with the present composition does not commence until the viral infection has progressed to the stage where the sores or blisters have burst, treatment takes somewhat longer. Once again, it is suitable to apply the composition to the infected area at intervals of about 1 hour initially, whereupon the sores normally dry, crust and start to shrink 24 hours, and complete disappearance of the external manifestations is obtained in 3-4 days, normally.

The glycerine in the formulation is believed to perform the function of maintaining tissue flexibility, and increasing the permeability of the cell membrane (surface vulnerability) to allow ready entry thereto of the ethyl alcohol, active ingredient. The glycerine prevents irritation from the alcohol/salt mixture. Less than about 2.5 parts by weight is ineffective in this purpose, but the upper limit of glycerine in the composition is largely determined by the solution stability and solubility of the glycerine in the chosen medium, rather than by reasons of technical effect. Of course, glycerine should not be used in such large amounts, even in a cream formulation, that it effectively masks the effect of the composition as a whole.

Whilst it is not intended that the invention should be limited to any particular theory of operation, it is believed that the compositions of the invention have an effect on the

interferon secreted by the applicable body cells. The composition, especially the ethanol, appear to stimulate appropriate interferon secreti ns from the virally infected cells, at least to assist in combatting the virus therein.

It is preferred to include an alkaline metal halide, preferably sodium chloride, in a liquid formulation according to the invention, so as to maintain proper saline compatibility with the body fluids. The preferred amount of sodium chloride is in accordance with standard medical practice in administration of saline solutions, to produce an isotonic solution, e.g. approximately 0.9% by weight of sodium chloride, in the total liquid solution. A preferred formulation according to the present invention comprises from 0 to 1 parts by weight of sodium chloride, from about 3 to about 5 parts by weight of glycerine, and from 3 to about 5 parts by weight of ethyl alcohol, along with approximately 90-100 parts by weight water, to make a homogeneous aqueous solution.

In making the aqueous solution formulation according to the present invention, no special temperatures or mixing equipment are necessary. Initially the salt and water are mixed together, then the alcohol is added, and finally the glycerine. Standard mixing and agitation techniques can be employed, to obtain a homogeneous solution, storable for up to 4 weeks without apparent loss of efficiency.

The invention is further illustrated in the following specific, non-limiting examples.

EXAMPLE 1

An aqueous solution according to the invention was made up of the following ingr dients:

0.9 parts by weight sodium chloride;

3 parts by weight glycerine;

4 parts by weight ethyl alcohol;

92.1 parts by weight water.

The ingredients were mixed in a standard mixing vessel, and a homogeneous solution prepared at room temperature by stirring agitation. The solution was then used to treat viral infections in humans, as described in the subsequent examples.

EXAMPLE 2

An adult male suffering from a common cold, manifested by constricted and inflamed nasal and sinus passages and other well known symptoms of a cold, administered to himself the composition as described in Example 1. Administration was performed topically, by filling a dropper with about 1 cc of formulation and depositing it into each nostril, and then working the composition into the nasal and post-nasal passages. This treatment, administration of 1 cc to each nostril from a dropper, was repeated at approximately 1 hour intervals. After a few hours, the patient noticed a significant improvement in terms of the constriction of his nasal passages and other painful symptoms resulting from the cold, and thereby decreased the frequency of dosage to intervals of about 2 hours, further

decreasing the frequency as the symptoms became all viated.

After 48 hours the patient r ported that all symptoms and manifestations of the cold had disappeared, and he felt and appeared completely cured.

EXAMPLE 3

An adult male human sufferer with herpes simplex type I viral infection, manifesting itself in a lip sore, treated the sore with the composition described in Example 1. Treatment commenced at the first noticeable development of the lip sore, when inflammation and swelling first became apparent before bursting had occurred, by application of the composition from an absorbent swab, at intervals of 1 hour. The pain and swelling soon began to decrease, with the repeated hourly treatment. By the following day, there had been a noticeable decrease in this swelling and a considerable relief of discomfort, so that the frequency of application of the composition was reduced to intervals of two hours. The improvement continued and the frequency of application was decreased therewith, until, after 72 hours from the commencement of treatment, the sore resulting from the viral infection had totally visably disappeared and the patient reported no residual discomfort.

EXAMPLE 4

A child of approximately 6 years of age reported for treatment with extensive HSV I infections manifesting themselves in a plurality of sores and blisters in the mouth area, some of

which had burst. The sores were treated topically with the liquid composition of Example 1, initially at intervals of 1 hour, and subsequently, as the sores began to dry and reduce in size, at intervals of two hours. The patient was reported to have made an excellent recovery, with all blisters and sores effectively disappeared, after about 4 days of this treatment.

EXAMPLE 5

An adult female patient suffered from HSV II infection, diagnosed as such by a gynecologist, and manifesting itself in a sore/blister in the vicinity of the patient's hip. This was reported to be a recurrence of a previous manifestation of HSV II infection in its active state. The hip sore was treated with the formulation described in Example 1, by topical application from a soaked swab of the formulation, at hourly intervals, gradually decreasing the frequency of application as the condition of the sore improved. After three days of such treatment, the patient reported that the sore was completely cured.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A pharmaceutical composition for topical application to virally infected sites of a mammal, said composition comprising:

from about 2.5 parts by weight to about 5.0 parts by weight of glycerine;

from about 1 to about 10 parts by weight of ethyl alcohol;

and from 0 to about 1 part by weight of a physiologically acceptable alkali metal halide salt.

2. The composition of claim 1 in the form of a topically applicable liquid solution, and additionally comprising from about 80 to about 100 parts by weight of water.

3. The composition of claim 1, wherein the alkali metal halide is sodium chloride, present in amounts of from about 0.8 to about 1 part by weight.

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